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Comparison of Topical Antibiotics Plus Intravenous Antibiotics Versus Intravenous Antibiotics Alone in Prevention of Surgical Site Infection in Inguinal Hernia Repair

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ABSTRACT

Background: Surgical site infections (SSIs) are a common complication following inguinal hernia repair, contributing to increased morbidity and healthcare costs. The role of combined topical and intravenous (IV) antibiotics in reducing SSIs remains debated.

Objective: To compare the efficacy of topical plus IV antibiotics versus IV antibiotics alone in preventing SSIs in inguinal hernia repair.

Methods: This randomized controlled trial included 400 male patients aged 20-70 years undergoing elective inguinal hernia repair under spinal anesthesia at Lahore General Hospital. Patients were randomly assigned to receive either IV cefazolin alone (Group B, n=200) or a combination of IV cefazolin and topical gentamicin (Group A, n=200). Patients were followed for 30 days postoperatively for SSIs. Data were analyzed using SPSS version 25.0, with significance set at $p \leq 0.05$.

Results: SSIs were significantly lower in Group A (2.5%, n=5) compared to Group B (9.5%, n=19) ($p=0.003$). The reduction was notable in patients aged >50 years ($p=0.040$), with BMI >25 kg/m^2 ($p=0.010$), smokers ($p=0.026$), and those with operative times >45 minutes ($p=0.035$).

Conclusion: The combination of topical and IV antibiotics significantly reduces SSIs in inguinal hernia repair, particularly in high-risk patients.

INTRODUCTION

Surgical site infections (SSIs) represent a significant concern in postoperative care, contributing to approximately 20% of all healthcare-associated complications. These infections can lead to extended hospital stays, increased treatment costs, and, in severe cases, necessitate additional surgical interventions. Globally, the incidence of SSIs in surgical patients ranges from 5% to 11%, with manifestations varying from minor wound oozing to life-threatening complications within thirty days post-surgery. In Pakistan, the overall incidence of SSIs is notably higher, reported at 29.8%, emphasizing the critical need for effective preventive strategies (1-4).

Inguinal hernia repair is among the most frequently performed surgical procedures worldwide and is typically classified as a clean surgery with an infection rate of under 5%. However, this rate can vary depending on the surgical setting and patient-specific factors. Local studies in Pakistan have reported infection rates of 4.01% to 5% following inguinal hernia repair, underscoring the need for context-specific preventive measures (4, 5, 6). While the routine use of antibiotic prophylaxis in such procedures is debated, it is generally considered in high-risk scenarios to enhance patient outcomes. Traditionally, intravenous (IV) antibiotics have been employed prophylactically in inguinal hernia repairs. Recently, the topical application of antibiotics has emerged as a supplementary approach, aiming to prevent microbial colonization of the surgical mesh and surrounding tissues, potentially reducing infection rates (7, 8).

The efficacy of combining topical antibiotics with IV antibiotics, compared to IV antibiotics alone, remains a subject of debate. Although some studies suggest that this combined approach may reduce infection rates, others have found the benefits to be minimal or statistically insignificant, highlighting a lack of consensus in the literature. This uncertainty underscores the necessity for further research, particularly within the context of inguinal hernia repair, where evidence from local settings remains scarce (9-12).

This study was designed to address this gap by comparing the frequency of SSIs in patients undergoing inguinal hernia repair who received a combination of topical and IV antibiotics versus those who received IV antibiotics alone. By analyzing clinical outcomes, the study aims to provide evidence-based guidance on the most effective prophylactic approach for minimizing SSIs in this common surgical procedure. This research is intended to

contribute meaningfully to the ongoing discourse on best practices for infection prevention in surgery, ultimately striving to improve patient outcomes and reduce the burden of SSIs in inguinal hernia repair within the local healthcare context.

MATERIAL AND METHODS

The study was designed as a randomized controlled trial (RCT) and conducted in the Surgical Unit I of the Surgery Department at Lahore General Hospital, Lahore, from February 2, 2023, to August 2, 2023. The sample size calculation was performed using the World Health Organization (WHO) sample size calculator, accounting for an 80% power of study, a 5% significance level, and a projected 3.1% incidence of surgical site infection with intravenous (IV) antibiotics alone, compared to 0% with the combined use of topical and IV antibiotics (13). This calculation yielded a total sample size of 400 patients, with 200 patients allocated to each group.

Patients were selected using a convenient sampling technique, including male individuals aged 20 to 70 years who were diagnosed with inguinal hernia and scheduled for repair under spinal anesthesia. The diagnosis of inguinal hernia was confirmed by a positive cough impulse and ultrasound findings. Exclusion criteria were defined to ensure a homogenous study population, excluding patients undergoing major surgical procedures for other abdominal viscera, emergency cases with obstructed or strangulated inguinal hernia, those with renal failure (creatinine >1.8 mg/dl), recurrent hernias, or those requiring repeat surgery due to previous failed surgery or infection at the surgical site.

Ethical approval for the study was obtained from the institutional review board (IRB) of Lahore General Hospital, and the study was conducted in accordance with the principles outlined in the Declaration of Helsinki. Informed consent was obtained from all participants prior to their inclusion in the study, ensuring their understanding of the study's objectives, procedures, potential risks, and benefits.

Patients were randomized into two groups using a lottery method to ensure unbiased allocation. Group A received a combination of IV antibiotics (1-gram cefazolin sodium by Eczacibasi, Istanbul, Turkey) administered as a bolus, along with topical antibiotics (gentamicin sulfate 80 mg 2% by Ulugay, Istanbul, Turkey) applied as a dressing on the wound. Group B received only the IV antibiotics (1-gram cefazolin sodium). All surgeries were performed by a single surgical team to minimize variability, and the procedures were standardized to maintain consistency in the surgical technique.

Patients were admitted to the surgical ward for 72 hours postoperatively and then discharged. Follow-up assessments were conducted in the outpatient department (OPD) over a 30-day period to monitor the development of surgical site infections (SSIs). SSIs were identified based on the presence of pain, tenderness, swelling, and pus discharge at the wound site. Any patient developing an SSI was treated according to the prevailing clinical guidelines.

Data collection was systematically carried out using a structured questionnaire to record baseline characteristics, including age, body mass index (BMI), duration of hernia, site of hernia, American Society of Anesthesiologists (ASA) physical status score, marital status, history of smoking, diabetes mellitus, hypertension, and family history of inguinal hernia. Intraoperative details such as the use of mesh, total operative time, and intraoperative blood loss were also meticulously documented.

The data analysis was conducted using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Quantitative variables such as age, BMI, duration of hernia, and operative time were presented as means with standard deviations, while qualitative variables such as marital status, smoking history, diabetes mellitus, hypertension, family history of inguinal hernia, ASA score, and presence of SSIs were expressed as frequencies and percentages. The chi-square test was utilized to compare the incidence of SSIs between the two groups, with a p-value of ≤ 0.05 considered statistically significant. Data were further stratified based on age, BMI, marital status, smoking history, diabetes mellitus, hypertension, family history of inguinal hernia, duration of hernia, site of hernia, and operative time, with post-stratification chi-square tests applied to identify significant associations (15).

RESULTS

This randomized controlled trial included a total of 400 patients who underwent inguinal hernia repair at Lahore General Hospital, Lahore. The patients were equally distributed between two groups: Group A, which received both intravenous (IV) and topical antibiotics, and Group B, which received only IV antibiotics.

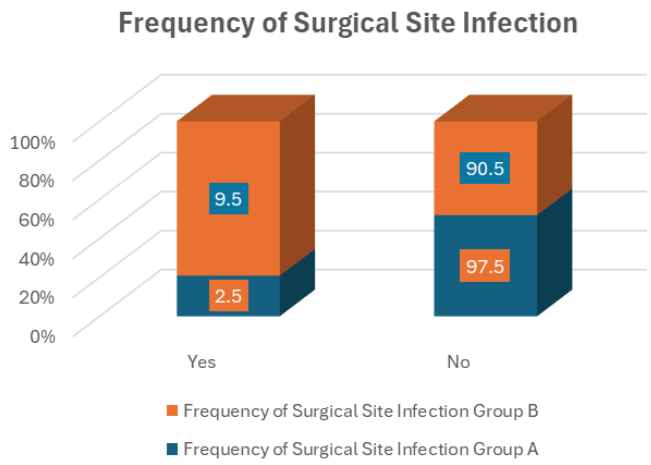

Figure 1 Surgical Site Infection

The baseline demographic and clinical characteristics of the patients are summarized in **Table 1**.

Table 1: Baseline Demographic and Clinical Characteristics of Patients in Both Groups (n = 400)

Characteristic	Group A (n = 200)	Group B (n = 200)	p-value
Age (years), Mean ± SD	45.24 ± 14.44	44.44 ± 14.72	0.581
BMI (kg/m²), Mean ± SD	27.12 ± 6.69	27.14 ± 6.73	0.976
Marital Status, n (%)			
- Married	95 (47.5%)	80 (40.0%)	0.131
- Unmarried	105 (52.5%)	120 (60.0%)	
History of Smoking, n (%)			
- Yes	85 (42.5%)	93 (46.5%)	0.421
- No	115 (57.5%)	107 (53.5%)	
Family History of Inguinal Hernia, n (%)			
- Yes	39 (19.5%)	32 (16.0%)	0.360
- No	161 (80.5%)	168 (84.0%)	
Diabetes Mellitus, n (%)			
- Yes	81 (40.5%)	79 (39.5%)	0.838
- No	119 (59.5%)	121 (60.5%)	
Hypertension, n (%)			
- Yes	80 (40.0%)	85 (42.5%)	0.612
- No	120 (60.0%)	115 (57.5%)	
Site of Hernia, n (%)			
- Left	101 (50.5%)	96 (48.0%)	0.617
- Right	99 (49.5%)	104 (52.0%)	
Duration of Inguinal Hernia (months), Mean ± SD	18.81 ± 11.24	18.36 ± 10.58	0.680
ASA Score, n (%)			
- ASA I	101 (50.5%)	96 (48.0%)	0.617
- ASA II	99 (49.5%)	104 (52.0%)	
Total Operative Time (minutes), Mean ± SD	45.35 ± 9.23	44.49 ± 8.61	0.336

No statistically significant differences were observed between the two groups in terms of age, BMI, marital status, smoking history, family history of inguinal hernia, diabetes mellitus, hypertension, site of hernia, duration of hernia, ASA score, or operative time, indicating that the groups were well-matched at baseline.

The overall incidence of surgical site infections (SSIs) in the study was 6.0%, with 24 patients developing SSIs. The comparison of SSI rates between the two groups is presented in **Table 2** and **Figure 1**.

Table 2: Comparison of Surgical Site Infections (SSIs) Between Groups A and B

Group	Number of Patients (n)	SSIs (n)	Incidence of SSIs (%)	p-value
A	200	5	2.5%	0.003
B	200	19	9.5%	

The incidence of SSIs was significantly lower in Group A (2.5%) compared to Group B (9.5%) (p = 0.003). This finding suggests that the combination of topical and IV antibiotics is more effective in preventing SSIs in patients undergoing inguinal hernia repair.

Further analysis was conducted to stratify the incidence of SSIs based on various demographic and clinical factors, as shown in **Table 3**.

Table 3: Stratification of Surgical Site Infections (SSIs) Based on Demographic and Clinical Characteristics

Characteristic	Group A (SSI +)	Group B (SSI +)	Total (SSI +)	p-value
Age (years)				
- ≤ 50	3 (2.4%)	11 (8.7%)	14 (5.6%)	0.032
- > 50	2 (2.6%)	8 (11.0%)	10 (6.7%)	0.040
BMI (kg/m²)				
- ≤ 25	2 (2.3%)	5 (6.0%)	7 (4.1%)	0.216
- > 25	3 (2.7%)	14 (12.0%)	17 (7.4%)	0.010
Marital Status				
- Married	1 (1.1%)	11 (13.8%)	12 (6.9%)	0.001
- Unmarried	4 (3.8%)	8 (6.7%)	12 (5.3%)	0.341
Smoking Status				
- Yes	2 (2.4%)	10 (10.8%)	12 (6.7%)	0.026
- No	3 (2.6%)	9 (8.4%)	12 (5.4%)	0.056
Diabetes Mellitus				
- Yes	0 (0%)	6 (7.6%)	6 (3.8%)	N/A
- No	5 (4.2%)	13 (10.7%)	18 (7.5%)	0.084
Hypertension				
- Yes	3 (3.8%)	7 (8.2%)	10 (6.1%)	0.228
- No	2 (1.7%)	12 (10.4%)	14 (6.0%)	0.005
Family History				
- Yes	1 (2.6%)	4 (12.5%)	5 (8.1%)	0.103
- No	4 (2.5%)	15 (8.9%)	19 (5.8%)	0.016
Duration of Hernia				
- ≤ 25 months	2 (1.5%)	11 (7.8%)	13 (4.8%)	0.015
- > 25 months	3 (4.4%)	8 (13.6%)	11 (8.7%)	0.068
Operative Time				
- ≤ 45 minutes	2 (2.0%)	9 (8.5%)	11 (5.3%)	0.037
- > 45 minutes	3 (3.0%)	10 (10.6%)	13 (6.7%)	0.035

Stratification revealed that the reduction in SSI incidence in Group A was particularly significant in patients aged over 50 years (p = 0.040), those with a BMI greater than 25 kg/m^2 (p = 0.010), smokers (p = 0.026), and those with a longer operative time (>45 minutes) (p = 0.035). These findings suggest that the combined antibiotic approach is especially beneficial in high-risk patient subgroups. The incidence of SSIs was also significantly lower in married patients in Group A compared to Group B (p = 0.001). Overall, the results of this study indicate that the

combination of topical and intravenous antibiotics is a more effective prophylactic strategy for preventing SSIs in inguinal hernia repair, particularly in patients with higher risk factors.

DISCUSSION

The findings of this study suggest that the combination of topical and intravenous antibiotics is significantly more effective in reducing the incidence of surgical site infections (SSIs) following inguinal hernia repair than the use of intravenous antibiotics alone. The overall reduction in SSIs from 9.5% in the intravenous-only group to 2.5% in the combined antibiotic group represents a clinically meaningful improvement, particularly in high-risk subgroups such as older patients, those with higher body mass index (BMI), smokers, and individuals undergoing longer operative procedures. These results align with some prior studies that have highlighted the potential benefits of adding topical antibiotics to standard prophylactic regimens, especially in surgeries involving the placement of foreign materials like mesh (17, 18).

Previous research has demonstrated mixed outcomes regarding the efficacy of combined antibiotic approaches in reducing SSIs. For instance, studies by Seker et al. and Troy et al. have shown that while the combination of topical and intravenous antibiotics may reduce bacterial colonization and subsequent infection, the results were not always statistically significant, leading to ongoing debate within the surgical community (11, 12). The findings from this study contribute to this discourse by providing robust evidence in favor of the combined approach, particularly within the context of inguinal hernia repair, a procedure with a relatively low but significant risk of infection.

The strengths of this study include its randomized controlled design, which minimizes selection bias and confounding factors, and the use of a standardized surgical protocol, which ensures consistency in the operative procedure across all patients. Furthermore, the study's focus on a well-defined surgical population and its rigorous follow-up protocol contribute to the reliability of the findings. The inclusion of a comprehensive range of demographic and clinical variables, such as age, BMI, smoking status, and operative time, allows for a nuanced analysis of the factors that influence SSI risk, thereby enhancing the generalizability of the results to similar clinical settings.

However, the study is not without limitations. The single-center design may limit the applicability of the findings to other healthcare settings with different patient demographics or surgical practices. Additionally, while the sample size was adequate for detecting differences in overall SSI rates, it may have been underpowered to detect more subtle differences in specific subgroups, such as patients with diabetes or those with longer hernia duration. Another limitation is the use of a convenient sampling method, which, while pragmatic, may introduce some degree of selection bias. Finally, the study did not assess the cost-effectiveness of the combined antibiotic approach, which is an important consideration in resource-limited settings where the additional cost of topical antibiotics may need to be justified by significant clinical benefits.

Despite these limitations, the study provides valuable insights into the potential advantages of combining topical and intravenous antibiotics in preventing SSIs in inguinal hernia repair. The statistically significant reduction in infection rates, particularly among high-risk patients, supports the adoption of this combined approach as a standard prophylactic measure in similar surgical contexts. Future research should focus on multicenter trials to validate these findings across diverse populations and healthcare systems. Additionally, studies assessing the cost-effectiveness of this strategy are warranted to determine its feasibility and sustainability in routine surgical practice.

In conclusion, this study underscores the importance of targeted infection prevention strategies in surgical practice. By demonstrating the superior efficacy of a combined antibiotic regimen in reducing SSIs, it contributes to the ongoing efforts to improve surgical outcomes and patient safety. The findings advocate for a reconsideration of current guidelines on antibiotic prophylaxis in inguinal hernia repair, particularly for patients at higher risk of postoperative infections.

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